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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,147	02/19/2004	Richard E. Weller	23-65308	5344

32215 7590 01/23/2007

KLARQUIST SPARKMAN, LLP
121 SW SALMON STREET, SUITE 1600
ONE WORLD TRADE CENTER
PORTLAND, OR 97204

EXAMINER	
PERREIRA, MELISSA JEAN	
ART UNIT	PAPER NUMBER
1618	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	01/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/784,147	WELLER ET AL.	
	Examiner	Art Unit	
	Melissa Perreira	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 February 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-35* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9 are drawn to a composition comprising a therapeutic agent, 90-yttrium phosphate, a therapeutic agent carrier, fibrin, and a stimulus sensitive gelling polymer, and one of a thermogelling, biodegradable polymer of a PEG-polyester block or biocompatible polymer block-biodegradable polypeptide block, classified in class 424, subclass 1.69.

II. Claims 10-18 are drawn to a composition comprising a therapeutic agent, 90-yttrium phosphate and a therapeutic agent carrier, a thermogelling, biodegradable polymer of a PEG-polyester block, classified in class 424, subclass 1.29.

III. Claims 19-25 are drawn to a composition comprising a therapeutic agent, 90-yttrium phosphate and a therapeutic agent carrier of a thermogelling, biodegradable polymer, such as a biocompatible polymer block-biodegradable polypeptide block, classified in class 424, subclass 1.29.

IV. Claims 26-34 are drawn to a method of making a therapeutic agent carrier comprising a stimulus-sensitive gelling polymer, fibrin or a combination and a therapeutic agent, 90-yttrium phosphate, classified in class 424, subclass 1.69 or 1.29.

V. Claim 35 is drawn to a method of treating cancer in a subject with a therapeutic agent carrier comprising therapeutic agent carrier comprising

a stimulus-sensitive gelling polymer, fibrin or a combination and a therapeutic agent, 90-yttrium phosphate, classified in class 424, subclass 9.322.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I,II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to compositions comprising a therapeutic agent, 90-yttrium phosphate and a therapeutic agent carrier, such as fibrin (group I), polymer of a PEG-polyester block (group II) or a polymer, such as a biocompatible polymer block-biodegradable polypeptide block (group III). The different compositions/inventions contain chemically and structurally different therapeutic agent carriers which would ultimately have different functional properties/characteristics. These stimulus sensitive gelling polymers are physically different, such as in the bonding and colloid forming characteristics and therefore they would react differently when subjected to external stimuli, such as pH, temperature, solvent composition, etc. The composition/invention of group I also includes fibrin as the therapeutic agent carrier and one of a thermogelling, biodegradable polymer of a PEG-polyester block or biocompatible polymer block-biodegradable polypeptide block, whereas the compositions/inventions of group II and III do not contain the fibrin therapeutic agent carrier but rely only on the thermogelling, biodegradable polymer to act as therapeutic agent carrier. The difference in the ratios of polymer to fibrin, which is a protein that polymerizes to form a

mesh, changes the functional characteristics of the resulting colloidal composition of group I, whereas the compositions only containing one of a thermogelling, biodegradable polymer of a PEG-polyester block or biocompatible polymer block-biodegradable polypeptide block will have more of a consistent colloidal dispersion. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

3. Inventions IV and I/II/III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case method of making a therapeutic agent carrier does not define the stimulus sensitive gelling polymer of the invention and therefore would require different reaction steps to make the products of the different inventions of groups I,II and III and also because the stimulus sensitive gelling polymer is not defined the preparation of the therapeutic carriers of groups I,II and III could be imagined via multiple reaction schemes. Since groups II and III do not contain the fibrin therapeutic agent carrier they would require different reaction schemes to make the materially different products. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not

required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

4. Inventions I/II/III and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the method of treating cancer in a subject can be accomplished with materially different products, which are described above (groups I,II and III). Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

5. Inventions IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are the method of making a therapeutic agent carrier and the method of treating cancer in a subject. Since the method of making a therapeutic agent carrier can generate different products, depending on the stimulus sensitive gelling polymer or use of fibrin, the method of treating cancer in a subject does not necessarily utilize the product from such as method. Therefore the inventions are not necessarily usable together. Because these inventions are independent or distinct for the reasons

given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an **election of an invention** to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
Due to the complex nature of the instant restriction requirement, a written restriction requirement was necessitated. See MPEP § 812.01.

6. Claims 1-35 are generic to the following disclosed patentably distinct species: thermogelling, biodegradable polymer:

a.) a PEG-polyester block

b.) a biocompatible polymer block-biodegradable polypeptide block

7. The species are independent or distinct because the different species contain chemically and structurally different therapeutic agent carriers (copolymer blocks) which would ultimately have different functional hydrogel properties/characteristics. These stimulus sensitive gelling polymers are physically different, such as in the bonding and colloid forming characteristics and therefore they would react differently when subjected to external stimuli, such as pH, temperature, solvent composition, etc.

8. **Applicant is required under 35 U.S.C. 121 to elect a single disclosed species**, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Perreira whose telephone number is 571-272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MP
January 18, 2007

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER